

ANALYTE: Helicobacter pylori
Antibodies (2513)

TEST SYSTEM, ASSAY,
EXAMINATION:

Quidel QuickVue One-Step H. pylori
Test for Whole Blood (52037)
SPECIALITY/SUBSPECIALITY:

Urinalysis
ANALYTE: Urine Dipstick or Tablet
Analytes, nonautomated (9641)

TEST SYSTEM, ASSAY,
EXAMINATION:

Bayer CHEK-STIX U.T.I. Test Strips
(07790)

Genesis Labs DIA SCREEN 10 Way
Reagent Strips: Urinalysis (22182)
TCPI URI-TEST Glucose in Urine
(61256)

TCPI URI-TEST Nitrite in Urine

(61257)

[FR Doc. 97-9350 Filed 4-10-97; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Procedures for Requests To Use
Child Care and Development Fund for
Construction or Major Renovation of
Child Care Facilities.

OMB No: New Collection.

Description: The Personal
Responsibility and Work Opportunity
Reconciliation Act of 1996 (Public Law
104-193) allows tribal grantees to use
Child Care and Development Fund
(CCDF) grant awards for construction
and renovation of child care facilities. A
tribal grantee must first request and
receive approval from the
Administration for Children and
Families (ACF) before using CCDF funds
for construction or major renovation.
This information collection contains the
statutorily-mandated uniform
procedures for the solicitation and
consideration of requests. Respondents
will be CCDF tribal grantees requesting
to use the CCDF funds for construction
or major renovation.

Respondents: Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Construction and renovation collection	100	1	20	2,000

Estimated Total Annual Burden Hours: 2,000.

In compliance with the requirements
of Section 3506(c)(2)(A) of the
Paperwork Reduction Act of 1995, the
Administration for Children and
Families is soliciting public comment
on the specific aspects of the
information collection described above.
Copies of the proposed collection of
information can be obtained and
comments may be forwarded by writing
to the administration for Children and
Families, Office of Information Services,
Division of Information Resource
Management Services, 370 L'Enfant
Promenade, S.W., Washington, D.C.
20447, Attn: ACF Reports Clearance
Officer. All requests should be
identified by the title of the information
collection.

The Department specifically requests
comments on: (a) whether the proposed
collection of information is necessary
for the proper performance of the
functions of the agency, including
whether the information shall have
practical utility; (b) the accuracy of the
agency's estimate of the burden of the
proposed collection of information; (c)
the quality, utility, and clarity of the
information to be collected; and (d)
ways to minimize the burden of the
collection of information on
respondents, including through the use
of automated collection techniques or
other forms of information technology.
Consideration will be given to

comments and suggestions submitted
within 60 days of this publication.

Dated: April 7, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97-9396 Filed 4-10-97; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 97M-0136]

Thoratec Laboratories Corp.; Premarket Approval of Thoratec® Ventricular Assist Device System

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice

SUMMARY: The Food and Drug
Administration (FDA) is announcing its
approval of the application by Thoratec
Laboratories Corp., Berkeley, CA, for
premarket approval, under the Federal
Food, Drug, and Cosmetic Act (the act),
of Thoratec® Ventricular Assist Device
System. After reviewing the
recommendation of the Circulatory
Systems Devices Panel, FDA's Center for
Devices and Radiological Health (CDRH)
notified the applicant, by letter of
December 20, 1995, of the approval of
the application.

DATES: Petitions for administrative
review by May 12, 1997.

ADDRESSES: Written requests for copies
of the summary of safety and
effectiveness data and petitions for
administrative review, to the Dockets
Management Branch (HFA-305), Food
and Drug Administration, 12420
Parklawn Dr., rm. 1-23, Rockville, MD
20857.

FOR FURTHER INFORMATION CONTACT: Dina
A. Justice, Center for Devices and
Radiological Health (HFZ-450), Food
and Drug Administration, 9200
Corporate Blvd., Rockville, MD 20850,
301-443-8262.

SUPPLEMENTARY INFORMATION: On June
26, 1992, Thoratec Laboratories Corp.,
Berkeley, CA 94710, submitted to CDRH
an application for premarket approval of
Thoratec® Ventricular Assist Device
System. The device is a ventricular
assist device and is intended as a bridge
to cardiac transplantation for use in
patients suffering from end-stage heart
failure. The patient should meet all of
the following criteria: (1) Candidate for
cardiac transplantation, (2) imminent
risk of dying before donor heart
procurement, and (3) dependence on, or
incomplete response to, continued
vasopressor support.

On December 5, 1994, the Circulatory
System Devices Panel of the Medical
Devices Advisory Committee, an FDA
advisory committee, reviewed and
recommended approval of the